IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

BRIAN EVANS, Plaintiff, vs. GILEAD SCIENCES, INC., et al., Defendant.	)	CIVIL NO. 20-00123 DKW-KJM MEMORANDUM IN SUPPORT OF MOTION

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INTRODUCTION

Gilead Sciences, Inc. ("Gilead") develops and markets life-saving medications, including Truvada®—an HIV medication containing tenofovir disoproxil fumarate ("TDF"). Plaintiff Brian Evans does not, and could not, allege that Truvada® was ineffective for treating or preventing HIV. Truvada® is approved by the U.S. Food and Drug Administration ("FDA") for the treatment and prevention of HIV infection; TDF-containing medications, including Truvada®, are core components of the U.S. Department of Health and Human Services' preferred regimens for HIV antiretroviral therapy[1]; and TDF is denominated as an "essential" medicine by the World Health Organization.[2]

Rather, Plaintiff was allegedly diagnosed with diffuse arthralgia (*i.e.*, joint pain) as a result of using Truvada®, and asserts two theories: (1) Truvada® was defectively designed because Gilead "had a 'safer medication'" containing tenofovir alafenamide ("TAF") that it allegedly should have introduced earlier; and (2) the Truvada® labeling did not adequately warn of bone risks associated with Truvada®, or the need for doctors to monitor patients for those risks. D.E. 8 at 2, 7;

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[1] *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, DEP'T OF HEALTH AND HUM. SERV., at G-4, G-19, G-25 (Dec. 18, 2019), https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.

[2] *WHO Model List of Essential Medicines*, WORLD HEALTH ORG., at 19-21 (2019), http://www.who.int/selection_medicines/list/en/.

see also D.E. 9 at 2-4 (summarizing claims). Plaintiffs' Amended Complaint should be dismissed for multiple reasons.

First, Plaintiff still has not pled a cognizable design defect theory. D.E. 7 at 5. While Plaintiff now asserts—in addition to his prior insufficient allegations, *id*.—that Gilead "refused to make [TAF-containing medications] available" earlier, D.E. 8 at 2, Gilead *did* introduce TAF-containing medications years before Plaintiff ever used Truvada®. Because Plaintiff alleges that his doctor chose to prescribe, and he chose to ingest, Truvada® *after* the availability of the alternative design that Plaintiff claims Gilead was required to introduce, Plaintiff has not identified a plausible design defect that proximately caused his alleged injury.

Second, Plaintiff has not pled a cognizable failure to warn claim. Rather, the FDA-approved Truvada® labeling is sufficient as a matter of law because, at all relevant times, that labeling warned of the bone risks that Plaintiff incorrectly claims were lacking and warned doctors to monitor patients for those risks. In all events, Plaintiff does not sufficiently allege causation—*i.e.*, that different warnings would have changed his doctors' prescribing decision.

Third, Plaintiff's fraud claim fails because he has not pled that claim with the required specificity. Plaintiff does not identify any misrepresentations that were allegedly made to him or his prescribing doctor, when he or his doctor was

exposed to any such misrepresentations, or if or how he or his doctor relied on any such misrepresentations.

Fourth, Plaintiff's breach of warranty claims fail, because Plaintiff has not pled facts supporting the elements of those claims, including any "warranty" or representation ever made to him or his doctors.

Fifth, while the above grounds are sufficient to dispose of Plaintiff's claims, those claims also are all preempted by federal law. Federal law preempts Plaintiff's design defect theory because Gilead could not have marketed the TAF-containing medications without first obtaining FDA approval. *See* 21 U.S.C. § 355(a) (requiring FDA approval to market a new drug); 21 C.F.R. § 314.70(b)(2)(i) (defining "changes in the qualitative or quantitative formulation of the drug product" as "major changes" that "requir[e] supplement submission and approval prior to distribution of the product"). Plaintiff's failure to warn theory is also preempted, because (a) a plaintiff cannot use state law to challenge, as inadequate, warnings contained in FDA-approved *original* labeling, and (b) Plaintiff fails to allege any "newly acquired information" that would have allowed Gilead to strengthen its Truvada® labeling warnings without prior FDA approval. Because all of Plaintiff's claims are based on one or both of these preempted design defect and failure to warn theories, they all should be dismissed.

BACKGROUND

A. TRUVADA® FOR PrEP

Truvada® is a "fixed-dose combination tablet[] containing emtricitabine and [TDF]."[3] On August 4, 2004, FDA approved Truvada® for treatment of HIV infection,[4] and on July 16, 2012, FDA approved Truvada® for use by HIV-negative adults as part of an HIV prevention regimen, known as pre-exposure prophylaxis ("PrEP").[5]

B. GILEAD'S TAF-CONTAINING MEDICATIONS

Between November 2015 and February 2018, FDA approved four TAF-containing medications ("TAF medications") for treatment of HIV.[6] One such

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[3] Center for Drug Evaluation and Research ("CDER"), Truvada® Approved Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_TruvadaTOC.cfm.

[4] CDER, Truvada® Approved Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_TruvadaTOC.cfm.

[5] U.S. Food & Drug Admin., "Truvada for PrEP Fact Sheet," https://www.fda.gov/media/83586/download.

[6] D.E. 8 at 8; *see also* CDER, Genvoya® Approved Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207561Orig1s000TOC.cfm; CDER, Odefsey® Approved Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208351Orig1s000TOC.cfm; CDER, Descovy® Approved Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208215Orig1_toc.cfm;

medication, Descovy® (approved on April 4, 2016), is particularly significant here, because it is a combination of TAF and emtricitabine and is, therefore, a TAF-containing analog to Truvada®.

C. PLAINTIFF'S COMPLAINT

Plaintiff alleges that in October 2018—***after*** FDA had approved all of the TAF medications—he was prescribed and began taking Truvada® for PrEP. D.E. 8 at 4, 6. Plaintiff does not allege that Truvada® was ineffective for PrEP. Instead, he alleges that, as a result of taking Truvada®, he experienced diffuse arthralgia (*i.e.*, joint pain). *Id.* at 2, 7.

Plaintiff further alleges that (i) Gilead "refused to make [TAF medications] available" at an earlier date, and (ii) the Truvada® labeling did not adequately warn of kidney and bone risks, or the need for doctors to monitor patients for those risks. D.E. 8 at 2, 7; *see also*, *e.g.*, *id.* at 3-4, 6; D.E. 9 at 2-4 (summarizing claims). Plaintiff asserts claims for design defect, failure to warn, fraud, and breach of express and implied warranty. D.E. 8 at 1; D.E. 9 at 1.[7]

CDER, Biktarvy® Approved Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210251Orig1s000TOC.cfm.

[7] Plaintiff also alleges that his healthcare provider prescribed Truvada® "without any testing or bloodwork." D.E. 8 at 1. He does not allege that Gilead was involved in that decision.

This Court dismissed Plaintiff's original Complaint [D.E. 1], without prejudice, because Plaintiff "ha[d] not alleged a design defect in Truvada," and had not sufficiently alleged that any purported defect or failure to warn "proximate[ly] cause[d]" his injuries. D.E. 7 at 5-6. The Court held that Plaintiff's Amended Complaint "may proceed such that Gilead may be served," but noted that "Gilead … may still challenge Evans' claims through any means procedurally permitted by the Federal Rules." D.E. 9 at 5.

D. GILEAD'S DISCLOSURE OF BONE RISKS FROM TRUVADA®

The FDA-approved Truvada® labeling has, at all relevant times, disclosed bone risks for all patients. For instance, the labeling when Plaintiff was allegedly first prescribed Truvada® disclosed, on the first page, the risk of "[d]ecreases in bone mineral density (BMD)." *See* Truvada® Approved Labeling (May 15, 2018) (Ex. A) at 1.[8] That labeling also describes "Bone Loss and Mineralization Defects," disclosing that "[i]n clinical trials … TDF (a component of TRUVADA) was associated with slightly greater decreases in bone mineral density (BMD)," and that "[c]ases of osteomalacia associated with proximal renal tubulopathy, manifested as bone pain or pain in extremities and which may contribute to

[8] The FDA-approved label for Truvada® is also available on FDA's website. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=021752.

fractures, have been reported in association with TDF use. ***Arthralgia and muscle pain or weakness have also been reported*** …" *Id*. at 7-8 (emphasis added); *see also, e.g., id*. at 8 ("ADVERSE REACTIONS" include "Bone Loss and Mineralization Defects"); *id*. at 12 ("In clinical trials of HIV-1 uninfected individuals, decreases in BMD were observed."); *id*. at 37 ("Bone problems can happen in some people who take TRUVADA. Bone problems include bone pain, or softening or thinning of the bones, which may lead to fractures."); *id*. at 33 ("Inform patients that decreases in bone mineral density have been observed with the use of TDF or TRUVADA.").

The labeling also informs doctors and patients regarding the need for "bone monitoring," and the need to "[m]onitor for evidence of tenofovir toxicity." *Id*. at 33 ("Consider bone monitoring in patients and uninfected individuals who have a history of pathologic bone fracture or at risk for osteopenia"); *id*. at 37 ("Your healthcare provider may need to do tests to check your bones."); *id*. at 1 ("Monitor for evidence of tenofovir toxicity.").[9]

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[9] Although Plaintiff also alleges that Gilead failed to warn of kidney risks associated with Truvada®, and the need to monitor for them, D.E. 8 at 2, 6, 7, he does not allege any kidney injury. Thus, the adequacy of Gilead's warnings regarding kidney risks is irrelevant to Plaintiff's claims. *E.g., Dash v. Roche Labs.*, 74 F.3d 1245 (9th Cir. 1996) ("A written warning is adequate if it directly warns … of the specific risk *that has caused injury to plaintiff*.") (emphasis added). Nevertheless, the Truvada® labeling also contained the kidney warnings that Plaintiff alleges were lacking. Ex. A at 1, 6-8, 33, 37.

LEGAL STANDARD

A pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "'[L]abels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.* "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* The plausibility standard requires a plaintiff to show "more than a sheer possibility that a defendant has acted unlawfully." *Id.*

Federal Rule 9(b) "requires that, when fraud is alleged, 'a party must state with particularity the circumstances constituting fraud ….'" *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting Fed. R. Civ. P. 9(b)). "Averments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Id.* "When an entire complaint, or an entire claim within a complaint, is grounded in fraud and its allegations fail to satisfy the heightened pleading requirements of Rule 9(b), a district court may dismiss the complaint or claim." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1107 (9th Cir. 2003).

On a motion to dismiss, courts may "consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment." *U.S. v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). "Even if a document is not attached to a complaint, it may be incorporated by reference into a complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Id.* Additionally, "records and reports of administrative bodies," such as "public documents available on the FDA's public website, … are proper subjects of judicial notice." *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1026 n.1 (D. Haw. 2014).[10]

"'[A] pro se litigant is not excused from knowing the[se] most basic pleading requirements.'" *Nosie v. Ass'n of Flight Attendants-CWA, AFL-CIO*, 722 F. Supp. 2d 1181, 1191 (D. Haw. 2010); *Doe v. Federal District Court*, 467 F. App'x 725, 727 (9th Cir. 2012) (although construed liberally, "even pro se

[10] Because Plaintiff "refers extensively to the" FDA-approved Truvada® labeling, and because it "forms the basis of" his failure to warn claim, that labeling is incorporated by reference into the Amended Complaint. *Ritchie*, 342 F.3d at 908. Gilead also requests that the Court take judicial notice of that labeling and the publicly-available information appearing on the FDA website referenced herein. Notwithstanding this request, and as set forth *infra*, Plaintiff's claims can be dismissed as preempted by federal law, and for failure to meet pleading requirements, even without reference to these materials.

pleadings 'must meet some minimum threshold in providing a defendant with notice of what it is that it allegedly did wrong.'").

ARGUMENT

I. PLAINTIFF HAS NOT ALLEGED A COGNIZABLE DESIGN DEFECT THAT PROXIMATELY CAUSED HIS INJURIES.

Plaintiff's original complaint did "not allege[] a design defect in Truvada," because Plaintiff's allegations that "Truvada is harmful to a consumer's kidneys and bones in 'high doses'" did not suffice to support his conclusion that Truvada® is defective. D.E. 7 at 5 ("if that were the legal standard for a design 'defect' virtually all medications (or any product consumed for that matter) could be deemed defective"). Plaintiff now also bases his design defect theory on allegations that Gilead "refused to make [TAF medications] available" at an earlier date. D.E. 8 at 1; *see also id*. at 3-4, 6-7.

But Gilead indisputably *did* make all of the TAF medications, including Descovy® (the TAF-containing analog to Truvada®), available before Plaintiff was ever prescribed, or ingested, Truvada® in October 2018. D.E. 8 at 4, 5 (alleging that Plaintiff was prescribed Truvada® in 2018, and that FDA approved the first TAF medication in November 2015); *supra* at 4-5 (describing FDA approval of all TAF medications, including Descovy®, before October 2018). In other words, Plaintiff's doctor chose to prescribe, and Plaintiff chose to ingest, Truvada® *after* the availability of the very medications that Plaintiff now alleges Gilead "refused

to make … available" and that purportedly "would have prevented Plaintiff['s] irreversible injuries." D.E. 8 at 1, 6. Plaintiff's insistence that Gilead *should have done* something that it indisputably *did* before he ever ingested Truvada® cannot form the basis of a design defect claim.

Nor can Gilead's purported "refusal to make" the TAF medications available earlier, or its alleged decision to "stop[] the production of the more reliable version of the drug," *id*. at 1, 4, constitute a "proximate cause" of Plaintiff's injuries. Gilead's alleged actions did not prevent the TAF medications from entering the market years before Plaintiff used Truvada®. *See* D.E. 7 at 6 (Plaintiff "has not alleged that a defect or hazard in Truvada (whether known or unknown) 'proximately [i.e., legally] caused' his joint pain") (quoting *Tabieros v. Clark Equip. Co.*, 944 P.2d 1279, 1313 (Haw. 1997)).

Rather, Plaintiff's basis for his design defect claim still "amounts to nothing more than 'an unadorned the-defendant-unlawfully-harmed-me accusation.'" D.E. 7 at 5. His design defect claim should be dismissed for failure to state a claim.

II. PLAINTIFF HAS NOT ALLEGED A COGNIZABLE FAILURE TO WARN THAT PROXIMATELY CAUSED HIS INJURIES.

Plaintiff fails to plead a failure to warn claim for two reasons: (1) the Truvada® labeling contained the warnings that Plaintiff incorrectly alleges were lacking; and (2) Plaintiff fails to adequately allege the causation required to sustain such a claim.

A. The FDA-Approved Truvada® Labeling Is Adequate As A Matter Of Law.

Plaintiff's failure to warn claim fails, because the Truvada® labeling has, at all relevant times, contained the bone and monitoring warnings that Plaintiff incorrectly alleges were missing. *See Dash*, 74 F.3d at 1245 ("A written warning is adequate if it directly warns in plain and explicit terms of the specific risk that has caused injury to plaintiff."); *Acoba v. Gen. Tire, Inc.*, 986 P.2d 288, 302 (Haw. 1999) (in some instances, "warnings may be found adequate as a matter of law").

Plaintiff's failure to warn claim is premised on allegations that Truvada® "could cause damage … to the bones of those who ingest it," but Gilead "failed to adequately disclose those dangers on Truvada's label," and "Gilead failed to properly warn patients of the side effects long after Plaintiff began taking the medication." D.E. 8 at 2, 6. Plaintiff also alleges that "Gilead intentionally omitted from its prescriber and patient labeling an adequate warning regarding the need for doctors to monitor all TDF patients on a frequent, specific schedule, for the adverse effects of TDF-associated bone … toxicity." *Id*. at 7.[11]

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[11] Hawaii follows the learned intermediary doctrine, pursuant to which Gilead owed any duty to warn to Plaintiff's doctor, not to Plaintiff himself. *See, e.g., Forsyth v. Eli Lilly & Co.*, No. Civ. 95-00185, 1998 WL 35152135, at *6 (D. Haw. Jan. 5, 1998) ("a drug manufacturer can presume that its warnings will be passed on from the prescribing physician to the ultimate patient/consumer under the 'learned intermediary' doctrine.") (citing *Bryant v. Tech. Research Co.*, 654 F.2d 1337, 1347 (9th Cir. 1981)).

The FDA-approved Truvada® labeling conclusively shows, however, that Gilead provided adequate warnings of bone risks and the need to monitor patients. Plaintiff was allegedly first prescribed Truvada® in October 2018. D.E. 8 at 4. Prior to that date, and at all times thereafter, the FDA-approved Truvada® labeling specifically warned of the bone risks that Plaintiff alleges were lacking, and of the need to monitor patients. *See supra* 6-7. For example, the label discloses—***on the first page***—that there is a risk of "[d]ecreases in bone mineral density (BMD)." Ex. A at 1. The labeling also extensively discloses, *e.g.*, additional "Bone Loss and Mineralization Defects," and the potential for "[b]one problems." *E.g.*, *id*. at 6-8, 12, 33, 37. In fact, it specifically warns of "arthralgia"—*the condition Plaintiff allegedly developed*. *Id*. at 7-8; D.E. 8 at 2, 7. And contrary to Plaintiff's allegations, the labeling also warns of the need to monitor patients for "the adverse effects of TDF-associated bone … toxicity." D.E. 8 at 7; *supra* 6-7; Ex. A at 1, 7, 33, 37 (instructing doctors to, *e.g.*, "[m]onitor for evidence of tenofovir toxicity," and "consider bone monitoring").

Because Gilead has warned doctors since before Plaintiff began taking Truvada® of the specific risks that he now alleges were missing—and indeed of the specific condition he allegedly experienced—his failure to warn claim fails as a matter of law. *E.g.*, *Dash*, 74 F.3d at 1245 ("Roche's package insert and brochure clearly and explicitly warned Dash's physician of the risks that the use of Accutane

might result in persistent or permanent dry eye condition. We conclude this warning was adequate as a matter of law."); *Zardo v. Merck & Co. Inc.*, 168 F.3d 504, 504 (9th Cir. 1999) (warning was adequate as a matter of law, where it "clearly states a risk of" the complained-of side-effect); *Adams v. Synthes Spine Co., LP*, 298 F.3d 1114, 1118 (9th Cir. 2002) (label was adequate as a matter of law, where "[i]t plainly stated that" complained-of adverse event could occur).[12]

B. Plaintiff Fails To Adequately Allege Warnings Causation.

Plaintiff's failure to warn claim also fails because he does not allege facts showing that the purportedly insufficient warnings in the Truvada® label *caused* his injuries. "[I]n order for a manufacturer to be liable for failing to provide an appropriate warning, it must not only be subject to a legal duty to warn, but the breach of that duty (*i.e.*, the failure to give an adequate warning) must have been the legal cause of the plaintiff's injuries." *Tabieros*, 85 Hawai'i 336, 370 (Haw. 1997). Thus, to adequately allege causation, Plaintiff must allege that his doctor would have acted differently (*e.g.*, not prescribed Truvada®) had Gilead provided supposedly adequate warnings. *E.g., Motus v. Pfizer Inc.,* 358 F.3d 659, 661 (9th

[12] *See also, e.g., Rollins v. Wackenhut Servs., Inc.*, 703 F.3d 122, 130 (D.C. Cir. 2012) (affirming dismissal where the "warning label warned of the precise risk of increased suicidal tendencies"); *Utts v. Bristol-Myers Squibb Co.,* 251 F. Supp. 3d 644, 674 (S.D.N.Y. 2017) (dismissing warning claim "because the warnings given on the [] label were, as a matter of law, sufficient to warn of" the alleged injury).

Cir. 2004) (warning claims fail "if stronger warnings would not have altered the conduct of the prescribing physician") (citations omitted).

Plaintiff alleges in conclusory fashion that "[i]ntentionally omitting the warnings from [the Truvada®] labeling caused the Plaintiff to be diagnosed with Diffuse Arthralgia, secondary to use of Truvada …." D.E. 8 at 1; *see also id*. at 7 ("The action or inaction has caused Plaintiff with Diffuse Arthralgia."). But he fails to plead facts to support this assertion, or the notion that some other warning would have prevented his arthralgia. Plaintiff does not allege that a purportedly adequate warning would have caused his doctor *not* to prescribe Truvada®.

Accordingly, his boilerplate recitation of causation does not suffice, and his claim should be dismissed. *Iqbal*, 556 U.S. at 678; *see also, e.g., Udac v. Takata Corp*., 121 Hawai'i 143, 163 (Haw. Ct. App. 2009) (rejecting claim where plaintiffs "presented no evidence that Takata's failure to warn in any way caused [the alleged] injuries"); *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1158-59 (S.D. Cal. 2015) (dismissing warning claim because plaintiff "failed to allege that if his prescribing physician had been warned, then he would not have prescribed the Patch to Plaintiff").[13]

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[13] *See also, e.g., Dunson v. Cordis Corp.*, No. l 6-cv-3076 , 2016 WL 3913666, *6 (N.D. Cal. July 20, 2016) (dismissing warning claim where plaintiffs "fail[ed] to allege facts that each prescribing physician would have acted differently upon rescript of proper warnings"); *Markowitz v. Davol Inc.*, No. 15-cv-2418, 2015 WL

III. PLAINTIFF FAILS TO PLEAD HIS FRAUD CLAIM WITH THE REQUISITE PARTICULARITY.

Plaintiff's fraud claim should be dismissed because it is not pled with the particularity required by Rule 9(b). Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). Common law fraud under Hawaii law requires "(1) false representations made by the defendant; (2) with knowledge of their falsity (or without knowledge of their truth or falsity); (3) in contemplation of plaintiff's reliance upon them; and (4) plaintiff's detrimental reliance." *Butler v. Onewest Bank, FSB*, Civ. No. 10-00300, 2010 WL 3156047, at *3 (D. Haw. Aug. 6, 2010). As set forth above, "[a]verments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Kearns v. Ford Motor Co.*, 567 F.3d at 1124; *see also Beavers-Gabriel*, 15 F. Supp. 3d at 1030 ("In their pleadings, Plaintiffs must include the time, place, and nature of the alleged fraud; 'mere conclusory allegations of fraud are insufficient' to satisfy this requirement.").

While Plaintiff asserts a fraud claim, D.E. 8 at 1, he does not plead the elements of such a claim, let alone with the particularity that Rule 9(b) requires.

12696031, *4 (C.D. Cal. June 19, 2015) (dismissing warning claim because "Plaintiff fail[ed] to sufficiently allege that his physicians would have altered their use of the Kugel Patch had adequate warning been provided").

Absent from Plaintiff's Complaint are any allegations about any misrepresentations ever made to him or his doctor, who made any such misrepresentations, when, where, or how any such misrepresentations were made, or how Plaintiff or his doctor relied on any such misrepresentation. More extensive allegations have been dismissed for failure to plead fraud with the required particularity, and here too, Plaintiff's fraud claim should be dismissed. *E.g.*, *Beavers-Gabriel*, 15 F. Supp. 3d at 1038 ("Missing from the Complaint … is the connection between Defendants' alleged misdeeds and Plaintiff and Plaintiff's physicians—*i.e.*, that Plaintiff and Plaintiff's physicians relied on these misrepresentations. Although the Complaint generally asserts that 'Plaintiff and Plaintiff's physicians … [relied] on Medtronic's concealment of information and misrepresentations about the safety risks related to [the device] in deciding to use [the device] … , the Complaint fails to identify what particular misrepresentations and/or concealments were made to Plaintiff and Plaintiff's physicians (as opposed to the medical field generally), who made those particular representations and/or omissions, and when those events occurred.").[14]

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[14] *See also Launiupoko Water Co., Inc. v. J-M Mfg. Co., Inc.*, No. 14-00303, 2014 WL 6685965, at *5 (D. Haw. Nov. 25, 2014) (dismissing fraud claim where "the complaint does not sufficiently identify the circumstances that constitute fraud, including such facts as the times, dates, places, or other details of the alleged fraudulent activity," or "how each Defendant could have intended to induce reliance by … Plaintiffs, with whom Defendants had no relationship"); *Patterson*

IV. PLAINTIFF FAILS TO SUFFICIENTLY PLEAD BREACH OF WARRANTY.

Plaintiff's breach of warranty claim also should be dismissed, because he fails to plead any facts to support the elements of this claim. A breach of express warranty claim "requires a plaintiff to establish 'that (1) Defendants made an affirmation of fact or promise regarding the product, (2) that statement became part of the basis of the bargain, and (3) the product failed to perform according to the statement.'" *Beavers-Gabriel*, 15 F. Supp. 3d at 1042 (quoting *Stoebner Motors, Inc. v. Automobili Lamborghini S.P.A.*, 459 F. Supp. 2d 1028, 1035 (D. Haw. 2006)). "In a breach of implied warranty of merchantability claim, Plaintiff must show (1) the seller is a merchant of goods, and (2) the product was defective or unfit for the ordinary purpose for which it is used. … In a breach of implied warranty for fitness of purpose claim, Plaintiff must prove that (1) Plaintiff desired a product for a particular purpose, (2) Defendants had reason to know about this

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v. Bayer Healthcare Pharms., Inc., No. 1:14-cv-1087, 2015 WL 778997, at *13 (E.D. Cal. Feb. 24, 2015) (dismissing fraud-based claims despite allegations that defendant's "label fail[s] to warn about" product risks, because "[a]bsent from these otherwise sufficient factual allegations is where or when [plaintiff] was exposed to the Booklet or other materials"); *In re Actimmune Mktg. Litig.*, No. 08-cv-2376, 2009 WL 3740648, at *11 (N.D. Cal. Nov. 6, 2009) (plaintiffs failed to satisfy Rule 9(b) where "neither individual alleges with any degree of specificity that they or their doctors ever were actually the recipient of any of defendants' fraudulent misrepresentations"), *aff'd*, 464 F. App'x 651 (9th Cir. 2011).

purpose, and (3) the product sold to Plaintiff failed to meet that purpose." *Launiupoko Water Co.*, 2014 WL 6685965, at *5 n.4.[15]

Plaintiff does not plead facts to support any warranty claim. He does not identify any warranty ever made to him or his doctor, let alone one that "became part of the basis of the bargain," nor how Truvada® failed to comply with some unspecified warranty. Plaintiff does not allege if or how Truvada® was "unfit for the ordinary purpose for which it is used," if or how Truvada® "failed to meet" the purpose for which it was desired, and, as set forth *supra* § I, Plaintiff has not alleged facts to support a theory that Truvada® is defective.

Thus, Plaintiff fails to plead facts to support the elements of his claim, and it should be dismissed. *See, e.g., Beavers-Gabriel*, 15 F. Supp. 3d at 1042-43 (dismissing breach of warranty claim, because plaintiff "fails to include any facts suggesting that those [identified] representations became the 'basis of the bargain' for Plaintiff and her physicians. Indeed, the Complaint fails to describe what specific warranties Medtronic made to Plaintiff and/or her physicians."); *Maeda v. Pinnacle Foods Inc.*, 390 F. Supp. 3d 1231, 1255 (D. Haw. 2019) (dismissing warranty claims as "insufficiently pled," because plaintiff did not allege "an affirmation of fact or promise sufficient to establish an express warranty," and

[15] Plaintiff did not indicate whether he purports to assert breach of implied warranty of merchantability or breach of implied warranty for a particular purpose.

plaintiff's implied warranty "claim rises and falls with [his] breach of express warranty claim"); *Launiupoko Water Co.*, 2014 WL 6685965, at *5 (dismissing warranty claims, because they "require more than the threadbare allegations set forth in the complaint").

V. FEDERAL LAW PREEMPTS ALL OF PLAINTIFF'S CLAIMS.

Plaintiff's claims all should be dismissed for the reasons set forth above, and the Court need go no further. But, Plaintiff's claims—all based on his design defect and failure to warn theories—are also preempted by federal law and may be dismissed on that independent basis.

A. Federal Regulations Regarding Drug Design and Labeling Changes.

The manufacture, use, and sale of drugs are regulated by the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 176 (S.D.N.Y. 2016), *aff'd by Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). Pursuant to the FDCA, a drug manufacturer must submit a new drug application ("NDA") to FDA and obtain its authorization before marketing or selling the drug. *Id*. at 177; *see also* 21 U.S.C. § 355(a). The NDA process "is both onerous and lengthy." *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 476 (2013). To obtain FDA approval of an NDA, a manufacturer must show that its drug is safe and effective. *Utts*, 226 F. Supp. 3d at 177 (quoting 21 U.S.C. § 355(b)(1)); *see also, e.g., McGee v. Boehringer Ingelheim Pharms.*,

Inc., No. 4:16-cv-2082, 2018 WL 1399237, at *3 (N.D. Ala. Mar. 20, 2018) ("Before the FDA permits a manufacturer to sell a new drug, the manufacturer must submit a new drug application and demonstrate that its drug is safe and effective."). FDA requires a manufacturer to demonstrate that its drug is "'safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling,'" and the manufacturer must "prove the drug's effectiveness by 'substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.'" *Utts*, 226 F. Supp. 3d at 177 (quoting 21 U.S.C. § 355(d)). Upon approval, a manufacturer is prohibited "from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved NDA.'" *Utts*, 226 F. Supp. 3d at 177 (quoting 21 C.F.R. § 314.70(b)(2)(i)).

Additionally, "FDA's premarket approval of an NDA includes the approval of the exact text in the proposed label." *Id*. (citing 21 U.S.C. § 355; 21 C.F.R. § 314.50(c)(2)(i), 314.105(b)); *McGee*, 2018 WL 1399237, at *3 ("FDA must approve the label's exact text before the manufacturer can sell the new drug."). Accordingly, FDA approval of drug labeling constitutes "a specific finding that [the drug's] label was not 'false or misleading in any particular.'" *In re Celexa &*

Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 36 (1st Cir. 2015) (quoting 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6)).

Like prohibitions on changes to an approved drug's *formulation*, a manufacturer may only change a drug *label* with FDA approval. *McGee*, 2018 WL 1399237, at *3. While a manufacturer may make certain changes to drug labeling without prior approval under the federal "changes being effected" ("CBE") regulation—*i.e.*, "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under" federal regulations—such changes must be based on "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii)(A). "Newly acquired information is data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3.

FDA "retains authority to reject labeling changes made pursuant to the CBE regulation." *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). "By expressly requiring that a CBE supplement only reflect newly acquired information and 'be based on sufficient evidence of a causal association,' the FDA ensures 'that scientifically

accurate information appears in the approved labeling.'" *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 659-60 (S.D.N.Y. 2017). FDA also recognizes that "'[e]xaggeration of risk, or inclusion of speculative or hypothetical risks [on drug labeling], could discourage appropriate use of a beneficial drug … or decrease the usefulness and accessibility of important information by diluting or obscuring it.'" *Utts*, 251 F. Supp. 3d at 659.

B. Federal Law Preempts Plaintiff's Design Defect Theory.

Plaintiff's design defect theory that Gilead should have marketed its TAF medications instead of Truvada® is preempted by federal law. As an initial matter, that theory fundamentally conflicts with FDA's specific approval of Truvada®. Moreover, Gilead's marketing of TAF medications in addition to, or in place of, Truvada® would have required prior FDA approval. Thus, it was impossible for Gilead to comply simultaneously with both a purported state law duty to introduce the TAF medications and federal law prohibiting Gilead from doing so unilaterally.

As the Supreme Court has held, "[w]here state and federal law directly conflict, state law must give way," and "state and federal law conflict where it is impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-18 (2011) (internal citations omitted). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id*. at 620. "[W]hen a party

cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id*. at 623-24. "[S]tate-law design-defect claims … that place a duty on manufacturers to render a drug safer by … altering its composition" are preempted, because they "conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition." *Bartlett*, 570 U.S. at 490.

The Sixth Circuit's decision in *Yates* is directly on point. Plaintiff asserted a design defect claim, alleging that defendants should have introduced a different formulation of their medication. *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015). Applying *Wyeth*, *Bartlett*, and *Mensing*, the court held that federal law preempted plaintiff's ***post***-approval design defect theory—*i.e.*, that defendants could have altered the drug's formulation after FDA approval—because "FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product ….' Therefore, to the extent [plaintiff] argues that defendants should have altered the formulation of [the product] after the FDA had approved the [product], we find this claim clearly preempted." *Yates*, 808 F.3d at 298 (quoting 21 C.F.R. § 314.70(b)(2)(i)).

The court also found that federal law preempted plaintiff's theory that defendants should have designed "a different drug in the first instance"—plaintiff's ***pre***-approval design defect theory—because defendants could not independently introduce an alternatively designed medication without FDA approval. *Id.* at 299-300. "Even if [state] law requires defendants to produce and market a different design, the ultimate availability to [plaintiff] is contingent upon whether the FDA would approve the alternate design in the first place…. Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing [the product], and certainly prior to [plaintiff's] use of the drug." *Id.*

The Connecticut Supreme Court also recently rejected a similar design defect claim "that the defendants could have brought [another drug] to market earlier." *Boone v. Boehringer Ingelheim Pharms., Inc.*, SC 20200, 2020 WL 2121063, at *12, 15, -- A.3d -- (Conn. May 4, 2020). The court held that "[b]ecause there is no dispute that [the drug] was not approved by the FDA until 2015, the defendants could not have satisfied their alleged state law duty to the decedent without marketing an unapproved drug in violation of federal law." *Id.* at *15.

Several courts have dismissed similar design defect claims, including those asserting, as here, that manufacturers should have sold a different product. *See,*

e.g., *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 14 (1st Cir. 2018) ("changing the product bottle so as to disperse a different amount of prescription eye solution is a 'major change' under 21 C.F.R. § 314.70(b)," such that "plaintiffs' attempt to use state law to require such a change is preempted"); *Fleming v. Janssen Pharm., Inc.* 186 F. Supp. 3d 826, 832-33 (W.D. Tenn. 2016) (dismissing as preempted design defect claim "premised on the proposition that Defendants should have designed Invokana differently"); *Utts*, 226 F. Supp. 3d at 185-86 (dismissing as preempted claims that "defendants had a pre-approval duty to submit a differently designed drug for FDA approval").[16]

Plaintiff's design defect theory is similarly premised on allegations that Gilead should have marketed the TAF medications instead of, or in addition to,

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[16] *See also, e.g., Robinson v. Eli Lilly & Co.*, 5:17-cv-338, 2018 WL 4039703, at *6 (E.D. Ky. Aug. 23, 2018) (pre- and post-approval design defect claims preempted because defendant "could not have independently made such fundamental changes to Prozac's formula"); *Drescher v. Bracco Diagnostics Inc.*, No. CV-19-00096, 2020 WL 1466296, at *5 (D. Ariz. Mar. 26, 2020) (dismissing design defect claim where "Plaintiff alleges that Defendants should have sold" a different drug formulation, because doing so "would require FDA approval," and "the Supreme Court expressly rejected Plaintiff's argument that Defendants should have simply replaced the linear GBCA products with macrocyclic GBCA products in *Bartlett*"); *Aston v. Johnson & Johnson*, 248 F. Supp. 3d 43, 54 (D.D.C. 2017) ("'state-law design defect claims … that place a duty on [pharmaceutical] manufacturers to render a drug safer by … altering its composition … are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling' and are therefore preempted") (quoting *Bartlett*, 570 U.S. at 490); *Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 154 (2017) ("In light of the statutes and regulations regarding new drug applications and preventing changes to drugs already approved by the FDA, defendants could not have 'unilaterally changed the active ingredient of Motrin from ibuprofen to dexibuprofen to satisfy their state law duty' without violating federal law."), *petition for review denied*, No. S243672 (Oct. 11, 2017).

Truvada®. But any such action would have required Gilead to obtain prior FDA approval. *See* 21 U.S.C. § 355(a) (requiring FDA approval to market a drug); 21 C.F.R. § 314.70(b)(2)(i) ("changes in the qualitative or quantitative formulation of the drug product" require supplemental submission to, and approval from, FDA); *see also* 21 C.F.R. § 314.70(h) ("An applicant may not supplement a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the approved 505(b)(2) application."). Thus, "to the extent [plaintiff] argues that [Gilead] should have altered the formulation of" Truvada® to include TAF instead of TDF, or sold the TAF medications instead of Truvada®, his claims are "clearly preempted." *Yates*, 808 F.3d at 298. In other words, "[e]ven if [state] law require[d] [Gilead] to produce and market a different design" or a different medication, Gilead could not do so under federal law "without ultimately seeking the FDA's approval." *Id.* at 299-300. Therefore, it "could not have satisfied [its] alleged state law duty … without marketing an unapproved drug in violation of federal law." *Boone*, 2020 WL 2121063, at *15. At bottom, Plaintiff's claim is that Gilead should only have sold purportedly safer "alternative drugs," despite the fact that FDA specifically authorized Gilead to market and sell Truvada®. Such

design defect claims are "incompatible with … pre-emption jurisprudence," and should be dismissed. *Bartlett*, 570 U.S. at 488; *Yates*, 808 F.3d at 300.[17]

C. Federal Law Preempts Plaintiff's Failure To Warn Theory.

Plaintiff's theory that Gilead failed to warn of bone risks associated with Truvada®, or the need to monitor for those risks, is also preempted by federal law, and should be dismissed.

Absent "newly acquired information" about safety, a manufacturer cannot change a drug's labeling without prior FDA approval. *See supra* § V.A; 21 C.F.R. § 314.70(b)(2)(v); *see also Utts*, 226 F. Supp. 3d at 177. Thus, failure to warn claims based on a purported state law duty to change a drug's original labeling,

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[17] In *Holley v. Gilead Sciences, Inc.*, 379 F. Supp. 3d 809 (N.D. Cal. 2019), plaintiffs asserted similar design defect claims regarding Gilead's TDF medications. The court noted that plaintiffs abandoned their ***post***-approval design defect claim, but held that even though Gilead could not have independently sold or marketed the TAF medications without FDA approval, plaintiffs' ***pre***-approval design defect claims were not preempted, because Gilead could have "develop[ed] and submit[ed] for FDA approval drugs that contained TAF rather than TDF …." *Id.* at 821, 822 n.6, 824 (N.D. Cal. 2019). The court incorrectly ignored that Gilead could not independently *market* any TAF medication "without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency …." *Mensing*, 564 U.S. at 623-24. Design defect claims are preempted where they would require an "NDA [for the allegedly alternative drug] to be marketed in interstate commerce." *Bartlett*, 570 U.S. at 484; *see also Boone*, 2020 WL 2121063, at *15 (the mere feasibility of "*develop[ing*] [the drug] before the decedent's death is insufficient to preclude preemption," because "that fact is inapposite to the question of whether *marketing* [the drug] in 2014 would have required FDA's 'special permission and assistance.'") (quoting *Mensing*, 564 U.S. at 623-24) (emphasis added)).

without an allegation of newly acquired safety information, are preempted. *Utts*, 251 F. Supp. 3d at 662-73 (dismissing warning claim because plaintiffs failed to allege "newly acquired information" that would have allowed defendant unilaterally to change its labeling). In *Gibbons*, the Second Circuit affirmed the *Utts* court's dismissal of failure to warn claims as preempted because plaintiffs did not adequately identify "newly acquired information." *Gibbons*, 919 F.3d at 707-08. Plaintiffs there alleged that "Defendants became aware of many reports of serious hemorrhaging" and that "numerous … studies published after [the drug's] approval in 2012 confirm the problematic bleeding events associated with [the drug]." *Id*. But, plaintiffs "provide[d] no basis upon which the court could conclude that the bleeding events covered by the alleged 'reports' and 'studies' presented a different type of risk than those the company had discussed with the FDA, or were more severe or more frequent that the bleeding events that the government already knew about," such that they did not constitute "newly acquired information" required for defendants to change the drug's labeling. *Id*.[18]

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[18] *See also, e.g.*, *Holley*, 379 F. Supp. 3d at 828, 830 (dismissing warning claims based on post-approval labeling as preempted, where "Plaintiffs allege that [Gilead] knew that TDF posed risks to patients' kidneys and bones before the first TDF drug was approved by the FDA," such that "the Court cannot conclude that Plaintiffs have plausibly alleged the existence of 'newly acquired information'—i.e., 'data, analyses, or other information not previously submitted to the FDA'") (quoting 21 C.F.R. § 241.3(b); emphasis omitted); *Drescher*, 2020 WL 1466296, at *3 ("Plaintiff's inadequate warning claim is preempted because it did not state a

Plaintiff has not alleged any "newly acquired information" and, thus, cannot state a non-preempted claim based on a purported post-approval failure to warn. To the contrary, Plaintiff alleges that "in 2001, when Truvada was approved," Gilead already "knew … it could cause damage to the kidneys and to the bones of those who ingest it." D.E. 8 at 2. Thus, any post-approval theory that Gilead should have revised the Truvada® labeling should be dismissed as preempted.

Plaintiff's failure to warn theory, therefore, is necessarily that FDA incorrectly approved the *initial* Truvada® labeling. But federal law preempts state law claims challenging, as inadequate, warnings contained in a drug's FDA-approved *original* labeling. *See*, *e.g.*, *Utts*, 226 F. Supp. 3d at 184-85 (dismissing claims, because "[t]o the extent that the failure to warn claims are premised on the adequacy of the label as approved by the FDA when the drug was first marketed in the United States, they are preempted"); *McGee*, 2018 WL 1399237, at *4 ("To the extent [plaintiff] asserts that [defendant] should have alerted the FDA about [the drug's] DKA risk *before* [the drug's] approval, the claim is preempted because the claim is essentially one of failure to communicate with the FDA."); *Patton v. Forest Labs., Inc.*, No. 17-cv-922, 2018 U.S. Dist. LEXIS 160368, *32 (C.D. Cal. Sept. 19, 2018) (dismissing failure to warn claim as preempted). Plaintiff cannot

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plausible claim that the Defendant manufacturers could have changed their labels under the [CBE] regulation").

use state law to "second guess … an FDA judgment," and FDA is "the exclusive judge of safety and efficacy based on information available at the commencement of marketing …." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d at 41; *see also Maze v. Bayer Healthcare Pharms., Inc.*, No. 4:18-cv-21, 2019 WL 1062387, at *3 (E.D. Tenn. Mar. 6, 2019) ("any claim asserted by Maze and based on information known to the FDA as of April 2012—when the label at issue here was approved—is plainly preempted by federal law").[19]

Thus, Plaintiff's claims based on allegedly inadequate warnings contained in the Truvada® labeling are preempted, and should be dismissed.

CONCLUSION

For the foregoing reasons, Plaintiff's Complaint should be dismissed. Because Plaintiff's Amended Complaint fails to cure the defects in his original Complaint, and because Plaintiff's claims fail for fundamental legal reasons that are not subject to cure, Plaintiff's claims should now be dismissed with prejudice. *See, e.g.*, *Gardner v. Martino*, 563 F.3d 981, 990 (9th Cir. 2009) (dismissal with

[19] The court's holding in *Holley*—that plaintiffs' pre-approval failure to warn claims were not preempted—is inconsistent with the above-referenced cases, which correctly and logically hold that failure to warn claims challenging the adequacy of an original label approved and deemed sufficient by FDA are preempted. *See Holley*, 379 F. Supp. 3d at 825; *see also supra* § V.A (explaining that FDA's approval of drug labeling constitutes "a specific finding that [the drug's] label was not 'false or misleading in any particular'").

prejudice is warranted where "amendment would be futile"); *Steele v. Cal. Dep't of Social Servs.*, 185 F.3d 869 (9th Cir. 1999) (dismissal with prejudice was appropriate where plaintiff failed to cure defects).

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/s/ Stefan M. Reinke
STEFAN M. REINKE
JOSHUA E. ANDERSON
(*pro hac vice petition forthcoming)*
ALYCIA A. DEGEN
(pro hac vice petition forthcoming)
Attorneys for Defendant
GILEAD SCIENCES, INC.